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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD. Defendants	:	Civil Action No. 07-634 (WHW)

COMPLAINT FOR DECLARATORY JUDGMENT

For their Complaint against Defendants Dr. Reddy's Laboratories Inc. ("DRL Inc.") and , Dr. Reddy's Laboratories Ltd. ("DRL Ltd."), Plaintiffs Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA") allege as to their own acts, and on information and belief as to the acts of others, as follows:

THE PARTIES

1. Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

2. Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly-owned subsidiary of Teva Ltd.

3. On information and belief, DRL Inc. is a corporation having a place of business at 200 Somerset Corporation Blvd. (Bldg. 11, 7th floor), Bridgewater, NJ 08807, and DRL Ltd. is a corporation having a place of business at 7-1-27 Ameerpet Hyperabad 500016 India.

NATURE OF THE ACTION

4. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 281-285.

JURISDICTION AND VENUE

5. This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

7. The Court has personal jurisdiction over DRL Inc. because of its presence within the New Jersey, and over DRL Ltd. because of its systematic and continuous contacts with the state of New Jersey.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400 (b) and/or 28 U.S.C. § 1391 (b) and (c).

BACKGROUND

The Patents In Suit

9. Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,600,073 ("the '073 patent"), 6,500,987 ("the '987 patent"), 6,495,721 ("the '721 patent"), and 6,897,340 ("the '340 patent"; collectively, "the patents in suit") relating to, *inter alia*, methods for manufacturing certain crystalline forms of a chemical compound known as sertraline hydrochloride. Two of these crystalline forms of sertraline hydrochloride are known as "Form II" and "Form V."

10. The '073 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on July 29, 2003 for an invention entitled "Methods for Preparation of Sertraline Hydrochloride Polymorphs." A copy of the '073 patent is attached as Exhibit [A].

11. The '987 patent was duly and legally issued by the PTO on December 31, 2002 for an invention entitled "Sertraline Hydrochloride Polymorphs." A copy of the '987 patent is attached as Exhibit [B].

12. Both the '073 patent and the '987 patent claim, *inter alia*, processes for preparation of sertraline hydrochloride Form V.

13. The '721 patent was duly and legally issued by the PTO on December 17, 2002 for an invention entitled "Sertraline Hydrochloride Form II and Methods For the Preparation Thereof." A copy of the '721 patent is attached as Exhibit [C].

14. The '340 patent was duly and legally issued by the PTO on May 24, 2005 for an invention entitled "Processes for Preparation of Polymorphic Form II of Sertraline Hydrochloride." A copy of the '340 patent is attached as Exhibit [D].

15. The '721 and '340 patents claim, *inter alia*, processes for the preparation of sertraline hydrochloride Form II.

Plaintiffs' Generic Exclusivity

16. Sertraline hydrochloride is a pharmaceutical compound useful in the treatment of depression. It is the active pharmaceutical ingredient ("API") in the product sold by Pfizer Inc. under the trade name ZOLOFT. Teva USA sells generic sertraline hydrochloride tablets in the United States that are manufactured by Teva Ltd.

17. Pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (1994) ("the Act"), Teva USA filed Abbreviated New Drug Application ("ANDA") No. 76-465 with the U.S. Food & Drug Administration ("FDA") for permission to market its generic sertraline hydrochloride tablets in the U.S.

18. Ivax Pharmaceuticals, Inc. ("Ivax"), a separate wholly-owned subsidiary of Teva Ltd., filed ANDA No. 75-719 with the FDA, also seeking permission to market generic sertraline hydrochloride tablets in the U.S.

19. Ivax's ANDA was approved on June 30, 2006. Under § 355(j) of the Act, Ivax obtained a limited period of exclusivity from the FDA for its generic sertraline products in the United States. Pursuant to this exclusivity, the FDA will not approve any other ANDA for generic sertraline hydrochloride tablets for a period of 180 days from the date Ivax first commercially marketed a product under its ANDA. This exclusivity period expires after February 6, 2007.

20. Ivax has selectively waived its exclusivity period with respect to Teva USA's ANDA No. 76-465. Following this selective waiver, the FDA granted final approval to Teva's ANDA on August 11, 2006.

Defendants' Imminent Infringement of the Patents In Suit

21. Under the Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. Suppliers of API typically are reluctant to disclose confidential information about their manufacturing processes to their customers. Such API suppliers typically submit this confidential information directly to the FDA in the form of a Drug Master File ("DMF"), which the FDA keeps on file. Customers of the API supplier who file ANDAs may then reference the DMF in their ANDAs. Upon receiving an ANDA referencing a DMF, the FDA will separately review the DMF as part of the ANDA approval process. Accordingly, the act of filing a DMF indicates the present intent of the filer is to supply API to at least one ANDA holder.

22. On information and belief, DRL Inc. has filed ANDA No. 076442 with the FDA and DRL Ltd. has filed DMF No. 16009 with the FDA, seeking permission to market generic sertraline hydrochloride tablets in competition with Plaintiffs.

23. On information and belief, the FDA has tentatively approved DRL Inc.'s ANDA, and will issue final approval upon the expiration of Ivax's exclusivity period.

24. On information and belief, DRL Inc. plans and intends to import, manufacture, use, sell and/or offer to sell in the United States its sertraline hydrochloride tablets immediately upon receiving final FDA approval. On information and belief, DRL Inc. plans and intends to engage in these activities prior to the expiration of the patents in suit.

25. On information and belief, the sertraline hydrochloride API contained in DRL Inc.'s tablets is or will be made by a process that infringes one or more of the claims of the patents in suit. Accordingly, DRL Inc.'s plans and intentions to import, manufacture, use, sell and/or offer to sell in the United States its sertraline hydrochloride tablets constitute imminent, threatened acts of infringement under 35 U.S.C. § 271(g), which give rise to an actual controversy over which this Court may exercise jurisdiction.

26. On information and belief, the sertraline hydrochloride API contained in DRL Inc.'s tablets is or will be Form II or Form V. On information and belief, sertraline hydrochloride Forms I, II and V are the only crystalline forms that are practical to use in a pharmaceutical tablet. On information and belief, Form I is claimed by an unexpired U.S. patent assigned to Pfizer Inc., and thus it is unlikely that DRL Inc. will attempt to market products containing that polymorph.

27. On information and belief, DRL Ltd. plans and intends to supply sertraline hydrochloride API to one or more third party ANDA holders, with the knowledge and intent that the third party ANDA holder(s) will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic sertraline hydrochloride tablets in the United States. Plaintiffs have made a reasonable effort to determine the identity of third party ANDA holder(s) that DRL Ltd. intends to supply. Currently, Plaintiffs are unable to obtain from a public source any information regarding the entities that DRL Ltd. intends to supply.

28. On information and belief, DRL Ltd. plans and intends to supply the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 27 immediately upon receiving final approval of the

ANDA(s) by the FDA, and that said approval will occur shortly after Ivax's exclusivity period expires.

29. On information and belief, DRL Ltd. plans and intends to supply the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 27 prior to the expiration of the patents in suit.

30. On information and belief, DRL Ltd. plans and intends to import sertraline hydrochloride into the United States for sale to third party ANDA holder(s).

31. On information and belief, DRL Ltd.'s sertraline hydrochloride API is or will be made by a process that infringes one or more of the claims of the patents in suit. Accordingly, DRL Ltd.'s plans and intentions to import and sell sertraline hydrochloride API in the United States constitute imminent, threatened acts of infringement under 35 U.S.C. § 271(g), which give rise to an actual controversy over which this Court may exercise jurisdiction.

32. On information and belief, DRL Ltd.'s plans and intentions to supply sertraline hydrochloride API to third party ANDA holder(s) outside of the United States for incorporation into products that it knows will be imported and sold in the United States constitute imminent, threatened inducement of infringement under 35 U.S.C. §§ 271(b) and (g), which gives rise to an actual controversy over which this Court may exercise jurisdiction.

33. On information and belief, DRL Ltd.'s sertraline hydrochloride API is Form II or Form V. On information and belief, sertraline hydrochloride Forms I, II and V are the only crystalline forms that are most likely to be used in a pharmaceutical tablet. On information and belief, Form I is claimed by an unexpired United States patent assigned to Pfizer Inc., and thus it

is unlikely that Defendant will attempt to market API containing that polymorph to customers intending to sell products in the United States.

34. On information and belief, Plaintiffs are not aware of any commercially viable process to manufacture Form V sertraline hydrochloride that is not covered by one or more claims of the '987 patent and/or the '073 patent. Thus, on information and belief, there is a substantial likelihood that the sertraline hydrochloride API in DRL's tablets, if Form V, is or will be made by a process that infringes one or more of the claims of the '987 patent and/or the '073 patent.

35. On information and belief, given the scope of Teva Ltd.'s patent rights to methods of making Form II, there is a substantial likelihood that the sertraline hydrochloride API in Defendant's tablets, if Form II, is or will be made by a process that infringes one or more of the claims of the '721 patent and/or the '340 patent.

36. On information and belief, given the scope of Teva Ltd.'s patent rights to methods of making Form II, there is a substantial likelihood that DRL Ltd.'s sertraline hydrochloride API, if Form II, is or will be made by a process that infringes one or more claims of the '721 patent and/or the '340 patent.

37. Plaintiffs have made a reasonable effort to determine the process by which DRL Ltd.'s sertraline hydrochloride API and the sertraline hydrochloride in DRL Inc.'s tablets is or will be made. Currently, Plaintiffs are unable to obtain from a public source, samples of DRL Ltd.'s API or DRL Inc.'s tablets or any information regarding the method used to manufacture the API used therein.

39. On information and belief, even if Plaintiffs had been able to obtain samples of Defendants' tablets and API from a public source or from Defendants, Plaintiffs are not aware of any analytical technique or combination of techniques that could be used to definitively establish that the sertraline hydrochloride API was made by one or more of the methods claimed in the patents in suit.

40. Plaintiffs, despite numerous efforts, have been unable to obtain Defendants process information or samples of API. Consequently, Plaintiffs have no choice but to resort to judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present to the Court evidence that Defendants will infringe the patents in suit.

41. On information and belief, Defendants' infringement will be willful and deliberate.

42. As a direct and proximate consequence of the planned and intended infringement by Defendants, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury and damages for which they are entitled to relief.

COUNT I
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

43. The allegations of paragraphs 1 to 42 are incorporated by reference as if fully set forth herein.

44. The importation, manufacture, use, sale and/or offer to sell by the DRL Inc. of its sertraline hydrochloride tablets pursuant to ANDA No. 076442 will infringe one or more claims of the '073, '987, '721 and/or '340 patents under 35 U.S.C. § 271.

45. The importation, manufacture, use, sale and/or offer to sell by the DRL Ltd. of its sertraline hydrochloride API pursuant to DMF No. 16009 will infringe one or more claims of the '073, '987, '721 and/or '340 patents under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the entry of a judgment from this Court:

a. Declaring that the '073, '987, '721 and '340 patents are valid and enforceable;

b. Declaring that Defendants will infringe one or more claims of the '073, '987, '721 and/or '340 patents;

c. Declaring that Defendants' infringement will be willful and that this is an exceptional case under 35 U.S.C. § 285;

d. Permanently enjoining Defendants, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '073, '987, '721 and '340 patents;

e. Awarding Plaintiffs damages in accord with 35 U.S.C. § 284;

f. Awarding Plaintiffs their attorneys fees, costs and expenses; and

g. Awarding Plaintiffs such other and further relief as this Court may deem to be just and proper.

LITE DEPALMA GREENBERG & RIVAS, LLC

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